

very first section of the Summary of the Invention in paragraph [0008] indicates that the invention was made in light of the above demands and it is an object thereof to present an alloy wire exhibiting superior corrosion resistance and wear resistance. Applicants also submit that the “superior corrosion resistance and wear resistance” is indicated in paragraph [0006] as being the result of a nickel-free fine wire in combination with a high Mo content. Furthermore, the Summary of the Invention indicates that the claimed alloy fine wire has “excellent biocompatibility” in paragraph [0008] and, in contrast, paragraph [0003] teaches that nickel is allergenic. Consequently, allergenic material cannot be a material exhibiting “excellent biocompatibility.” Furthermore, in paragraph [0003], it is clearly stated that it is “preferred not to contain nickel in fine-wire used in the medical field” (emphasis added). Thus, it is clear that one of the purposes of the present invention is to obtain an alloy fine wire that is not allergenic, and that does not contain any nickel, especially when used in the medical field. Finally, the Summary of the Invention clearly indicates that the invention is made “in light of the above demands,” the above demand being that the alloy fine wire should be “nickel-free.” Accordingly, Applicants respectfully submit that the Specification does provide the sufficient support for the feature of the alloy being nickel free. Thus, independent claims 1 and 15 fulfill the requirements of 35 U.S.C. § 112, first paragraph. As such, withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph, is respectfully requested.

The Office Action rejects claims 1-4, 11-16 and 23-26 under 35 U.S.C. § 103(a) as being obvious over Stinson (U.S. Patent No. 5,891,191). The rejection is respectfully traversed.

In particular, the above-identified application claims a cobalt-chromium-molybdenum alloy fine wire for biomaterials consisting of 26 to 31 weight % of chromium, more than 8 weight % to 16 weight % of molybdenum, and the remainder of cobalt and inevitable impurities, the alloy being nickel-free, and the wire having a degree of roundness of a lateral cross section of 0.6 or more, as recited in independent claim 1, and similarly recited in independent claim 15.

Stinson teaches a self-expanding stent formed of helically wound and braided filaments of wrought cobalt, chromium and molybdenum alloy containing less than about five weight percent nickel (Abstract). Stinson also teaches, as also indicated in the October 1, 2007, Office Action by the Patent Office, a content of molybdenum that is "between about 4-8 weight percent molybdenum" (column 3, line 44). Furthermore, nowhere else in Stinson is there any teaching of a broader range or a higher range of molybdenum content. Accordingly, by the clear teaching of a molybdenum content "between 4 and 8 weight percent," Stinson clearly fails to teach having more than 8 weight percent to 16 weight percent of molybdenum, as recited in independent claims 1 and 15. A range of "between 4 and 8 percent" is a different range than "more than 8 percent," and the higher range of the more than 8 percent Mo in this case provides a better corrosion resistance and wear resistance, as indicated in the Specification at, for example, paragraph [0004]. Thus, obtaining a range of Mo of more than 8 percent is not obvious based on the teachings of Stinson.

Furthermore, with respect to the recitation in claims 1 and 15 of "a roundness of lateral cross section of 0.6 or more," the current Office Action refers to the October 1, 2007, Office Action, which clearly indicates that filaments #12 of the cobalt alloy are

substantially homogeneous in cross section, and that the concentration ratio of molybdenum, chromium or cobalt teaches that the composition of the wires is also substantially homogeneous (October 1, 2007, Office Action, page 3, lines 8-12). However, these teachings are relative to concentrations of molybdenum, chromium or cobalt and are different from the claimed roundness which is a ratio of minor diameter over major diameter, as clearly indicated in claims 1 and 15. In fact, a closer examination of Stinson reveals that there is no indication anywhere of a degree of roundness, *i.e.*, of a ratio of a minor diameter over a major diameter, and the Office Action misconstrued the feature of the degree of roundness to be equivalent to homogeneity in concentration of the various components of the alloy, as clearly shown in the October 1, 2007, Office Action. In fact, Stinson clearly does not teach anywhere a degree of roundness, which is the ratio of a minor diameter over a major diameter of a lateral cross section of the wire being of 0.6 or more, as recited in independent claims 1 and 15.

Finally, with respect to the feature of the wire being nickel-free, the current Office Action indicates that because Stinson teaches a ratio of nickel that is "less than about two weight percent nickel," that a percentage of zero percent nickel is part of this recitation. However, the Office Action is mistaken for the following reasons.

Stinson clearly teaches a chromium, cobalt, molybdenum alloy that includes nickel, as evidenced in the Abstract, in which the representative embodiment of the teachings of Stinson includes 1% nickel. Furthermore, Stinson indicates in various portions of the Specification, that nickel enhances the ductility of the alloys, improving its ability to be mechanically drawn or formed (column 2, lines 3-6), and that materials

commonly used for self-expanding stint filaments include Elgiloy® and Phynox® which are cobalt-based alloys which also include chromium, iron, nickel and molybdenum (column 1, lines 44-50). Although these teachings of Stinson are in the background of the invention, Stinson clearly indicates in the Summary of the Invention that Stinson's invention relates to an improved implantable medical device comprised of a tubular and radially expandable structure from the cobalt, chromium, molybdenum alloy containing less than about 5 weight percent nickel, or containing less than about 2 weight percent nickel (column 3, lines 31-44). Although a theoretical interpretation of the teachings of "less than about" either 5 weight percent or 2 weight percent may allow for the inclusion of a nickel-free alloy in this range, the teachings of Stinson must be read in light of the entirety of the Specification including the Background section, which clearly teaches that the various alloys used to date typically contain 10 to 20 percent nickel, and that the improvement over the background art is to decrease the level of nickel from 10 to 20 percent to less than 5 or less than 2 weight percent, not to eliminate it in view of the above-listed advantages of having nickel in the alloy. The test here is whether the ordinary person skilled in the art would construe the teaching of "less than 5 percent" or "less than 2 percent" as including 0 percent (i.e., nickel-free). Applicants respectfully submit that in light of the overall teachings of the Stinson reference, including the Background section which clearly teaches the beneficial presence of nickel in the alloy, the reading of "less than 5 percent" or "less than 2 percent" by the ordinary person skilled in the art cannot include the possibility of having a nickel-free alloy. For this reason, Stinson fails to disclose or suggest an alloy that is nickel free.

For at least the reasons above, Stinson fails to disclose, suggest or render obvious each and every feature of independent claims 1 and 15. Thus, independent claims 1 and 15 are patentable over Stinson. Furthermore, claims 2-4, 11-14, 16 and 23-26, at least for their dependence on patentable claims 1 and 15, and for their added limitations, are also patentable over Stinson. Thus, all of the pending claims are patentable over Stinson, and withdrawal of the rejection of the claims under 35 U.S.C. § 103(a) is respectfully requested.

Should the Examiner determine that any further action is necessary to place this application into better form, the Examiner is encouraged to telephone the undersigned representative at the number listed below.

In the event this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing Attorney Dkt. No. 108421-00096.**

Respectfully submitted,



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